

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Steven M. RUBEN

Appl. No.: 10/662,429

Filed: September 16, 2003

For: **Apoptosis Inducing Molecule I**

Confirmation No.: 2663

Art Unit: 1644

Examiner: HUYNH, PHUONG N.

Atty. Docket: 1488.1890003/EJH/SAC

**Declaration of Scott Conklin
Ruben Exhibit #18**

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Ruben EXHIBIT #18

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Filed on Behalf of Party Ruben

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Administrative Patent Judge Sally Gardner Lane)

STEVEN M. RUBEN

Junior Party,
(Application 08/816,981),

v.

STEVEN R. WILEY and RAYMOND G. GOODWIN

Senior Party,
(Patent No. 5,763,223).

Patent Interference No. 105,077

DECLARATION OF SCOTT CONKLIN

Ruben EXHIBIT 2018
Ruben v. Wiley et al.
Interference No. 105,077
RX 2018

DECLARATION OF SCOTT CONKLIN

I, SCOTT CONKLIN, declare and state as follows:

1. I have been employed by Pocono Rabbit Farm & Laboratory Inc. ("PRF&L") since 1992. During my career at PRF&L, I have been closely involved in the process of raising antibodies in rabbits against proteins sent to PRF&L by our customers and providing our customers with resultant antiserum by both supervising and directly carrying out the immunization, bleeding, and shipping processes.

2. RE19 is a copy of an agreement signed by Dr. Daniel Bednarik on July 23, 1993 as "principal investigator" on behalf of Human Genome Sciences, Inc (HGS). Based on my personal experience of servicing at least 100 antibody projects for HGS since July of 1993, I know that Dr. Bednarik was listed as the general principal investigator for many of the HGS projects carried out by PRF&L through at least 1996.

3. RE24 is a letter from Ann M. Kim, dated June 26, 1995, to Cindy Haab of PRF&L, enclosing two tubes of "FasLig" protein, for antibody production, requesting that PRF&L produce anti-"FasLig" antibodies by its standard protocol for fusion protein antigens. The letter was stamped as having been received by PRF&L on June 28, 1995.

RE24

4. RE20 is a copy of the PRF&L Lab Book Record for rabbits 11940 and 11941. As the Lab Book Record indicates, a protein referred to as "FasLig" was received from investigators Bednarik and Ann M. Kim on or before June 30, 1995. I personally supervised the raising of antisera against "FasLig" in rabbits 11940 and 11941 on behalf of HGS. RE21 is a copy of the Health Cards for rabbits 11940 and 11941. The Health Cards of RE21 provide a more detailed description of the protocol used in

raising the anti-"FasLig" antiserum in rabbits 11940 and 11941, including the initials of the technicians who actually handled each rabbit under my supervision. Attached hereto as RE22 is a print out of the PRF&L electronic record of all bleeds of rabbits 11940 and 11941 that were shipped by PRF&L to HGS (information pertaining to other rabbits is redacted from RE22). The dates in the fifth column of RE22 are the record dates corresponding to each bleed (i.e., the date the bleed was entered into the record keeping system). In each case, the record date is the Friday immediately following the actual bleed date. The actual bleed dates are contained on the Health Cards of RE21. The shipping dates for each bleed are shown on the respective front pages of each of the record listings contained in RE22. As has been our usual practice since prior to June of 1995, the post-immunization bleeds of rabbits 11940 and 11941 were each sent to HGS the Monday immediately following the actual bleed date, except when the Monday was a holiday.

5. Each of RE20, RE21, and RE22 was prepared and maintained according to PRF&L standard business practices, which recorded activities contemporaneously with such activities. As shown collectively in RE20, RE21 and RE22, both rabbit 11940 and 11941 underwent a continuous antiserum production protocol, entailing a series of immunizations, bleedings, and shipments of antisera, over the course of approximately six months from June 30, 1995 to January 2, 1996. Each bleeding is intended to capture antibodies that the rabbit was continually raising against the protein injected in the prior immunizations. More specifically, as shown in RE21 and RE22, the following protocol was carried out:

- On June 30, 1995, each rabbit was weighed, a pre-immune bleed of 8 ml was taken from each rabbit (record date of bleed was also June 30, 1995), and each rabbit was given a 0.5 ml intradermal (ID) and subcutaneous (SC) injection of the "FasLig" protein;
- On July 27, 1995, each rabbit was given a 0.5 ml ID and SC injection of the "FasLig" protein;
- On August 11, 1995, each rabbit was given a 0.5 ml SC injection of the "FasLig" protein;
- On August 23, 1995, each rabbit was weighed, a bleed of 8 ml was taken from each rabbit (record date of bleed was August 25, 1995), and each rabbit was given a 0.5 ml intravenous (IV) and subcutaneous (SC) injection of the "FasLig" protein;
- On Monday, August 28, 1995, the pre-immune bleeds of June 30, 1995 and the post-immunization bleeds of August 23, 1995 were sent to HGS.
- On August 29, 1995, each rabbit was weighed and a bleed of 30 ml was taken from each rabbit (record date of bleed was September 1, 1995). The bleeds were sent to HGS on September 5, 1995;
- On September 8, 1995, each rabbit was given a 0.5 ml SC injection of the "FasLig" protein;
- On September 19, 1995, each rabbit was weighed, a bleed of 30 ml was taken from each rabbit (record date of bleed was September 22, 1995). The bleeds were sent to HGS on September 25, 1995;

- On October 6, 1995, each rabbit was given a 0.5 ml SC injection of the "FasLig" protein;
- On October 17, 1995, each rabbit was weighed, and a bleed of 30 ml was taken from each rabbit (record date of bleed was October 20, 1995). The bleeds were sent to HGS on October 23, 1995;
- On October 24, 1995, rabbit 11940 was examined and from October 24 to October 26, 1995, rabbit 11940 received a treatment of oxytet 200 injections for health reasons;
- On October 26, 1995, rabbit 11941 was examined and from October 26 to October 28, 1995, rabbit 11941 received a treatment of oxytet 200 injections for health reasons;
- On October 30, 1995, rabbit 11941 received another oxytet 200 injection;
- On November 1, 1995, rabbit 11940 received another oxytet 200 injection;
- On November 3, 1995, each rabbit received a 0.5 ml injection of the "FasLig" protein;
- On November 4, 1995, rabbit 11940 received another oxytet 200 injection;
- On November 5, 1995, rabbit 11941 received another oxytet 200 injection;
- On November 15, 1995, rabbit 11941 was weighed, and a bleed of 30 ml was taken from the rabbit. On November 16, 1995, rabbit 11940 was weighed, and a bleed of 28 ml was taken from the rabbit. The record date of each bleed is November 17, 1995. The bleeds were sent to HGS on November 20, 1995;
- On November 30, 1995, each rabbit received a 0.5 ml injection of the "FasLig" protein;

- On December 4, 1995, rabbit 11940 was moved to its normal cage;
- On December 12, 1995, each rabbit was weighed and a bleed of 30 ml was taken from each rabbit (record date of bleed was December 15, 1995). The bleeds were sent to HGS on December 18, 1995;
- On December 27, 1995, each rabbit was exsanguinated (record date of bleed was December 29, 1995). The bleeds were sent to HGS on January 2, 1996 for receipt on January 3, 1996.

6. Once an immunization is initiated, a schedule of immunization and care is triggered and proceeds along a continuous time course that is generally dictated by the rabbit's biology. Such a typically continuous time course was followed in the case of rabbits 11940 and 11941. More specifically, the protocol set forth in paragraph 5, above, was carried out in general accordance with the standard protocol for polyclonal rabbit antiserum production for protein that PRF&L has been carrying out since the time of this project. RE23¹ is a printout of PRF&L's standard protocol as presented on its web-site in 2000, which is substantially the same as the protocol used in 1995. The time course of injections and bleedings followed for rabbits 11940 and 11941 was in close accordance with this standard protocol, as it is commonly continued beyond Day 70. The initiation of such a continuation, as occurred with rabbits 11940 and 11941, is carried out only at the request of the customer. Moreover, as indicated in RE23¹, an exsanguination at termination, as occurred with rabbits 11940 and 11941, is carried out only when such additional antiserum is requested by the customer. Also as indicated in RE23¹, peak antibody titer (which is tested by the customer and not by PRF&L) occurs anywhere between six weeks and a year. The overall duration of the protocol for rabbits 11940 and

11941 of approximately six months is quite typical of the hundreds of projects I have carried out and supervised for HGS, as well as the many others I have supervised over my career.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application captioned above or any patent issuing thereupon.

Date: 6.20.2004 
Scott Conklin

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